Remarks

Upon entry of the amendments to the claims and the foregoing remarks, claims 1-36 are pending in this application. Claims 17-34 and 36 are considered allowable. Claims 1-16 and 35 are currently under rejection. Claims 37 and 38 are new. Claim 1 has been amended.

Rejections under 35 U.S.C §102

The Examiner has rejected Claims 1-13 and 35 under 35 USC §102(b) as allegedly being anticipated by Bredt et al, U.S. Patent Serial Number 5,085,561 (hereafter "Bredt"). The Examiner is of the opinion that Bredt teaches the claimed product as an intermediate product in the methods for purification of a 168 kD protein from *M. pneumoniae* using zwitterionic and non-ionic detergents. The applicant respectfully disagrees and traverses the rejection.

The Examiner has pointed to sections of Bredt that allegedly support the rejection, namely the abstract, column 2 lines 29-39 and column 3, line 24 to column 4 line 32 as well as Example 2 of Bredt. Applicant would like to point to column 3, lines 17-33 of Bredt to argue the above noted rejection.

The passage states

> *"In a first step in the method, the complete cells of* M. pneumoniae *are pretreated with CHAPS, resulting in the major amount of the proteins, including the 145 kD protein and a small amount of the 168 kD protein, being dissolved. The resulting homogenate is centrifuged and then aliquots of the pellet are solubilized with various concentrations of octylglucoside.*
>
> *Preferably used for the first step in the treatment of the whole cells of* M. pneumoniae *is a buffer mixture (buffer I) which contains the zwitterionic detergent CHAPS in a concentration of about 0.1-10% (w/v), preferably 1% (w/v).*
>
> *The pellet obtained after the first step in the dissolution is preferably treated with the nonionic detergent octylglucoside likewise using a buffer mixture (buffer II) which contains octylglucoside in a concentration of about 0.1-10% (w/v), preferably 1-2% (w/v)."*

Applicant believes that the Examiner's conclusion of anticipation is incorrect. Column 3, lines 17-33 of Bredt (above) refers to a whole cell homogenate which would not be understood to be suitable for injection in a human as required by the claim : "*a non-painful composition of* ***a hydrophobic protein suitable for injection in a human*** *comprising: (a)* ***a hydrophobic***

protein; *(b)an amount of a zwitterionic detergent* ***that is less than the amount required to solubilize the protein;*** *and (c) an amount of a pharmaceutically acceptable nonionic detergent effective to maintain solubility of the protein in a pharmaceutically acceptable carrier.* It is clear from the context of the application as filed as to the types of protein suitable for injection, see for e.g. Example 1 page 32 line 10 which refers to 'clinical grade' proteins. Additionally, as the Examiner points to on page 3 of the Office Action dated January 7, 2009, Bredt teaches an intermediate in the method of purification of a protein, but does not teach or suggest using this intermediate as an immunogenic composition, as in Applicant's claimed invention. Furthermore, newly added claims 37 and 38, both supported on page 17 of the instant specification, recite an immunogenic composition that further comprises a pharmaceutically acceptable carrier or an adjuvant. Bredt does not teach or suggest an immunogenic composition with or without a pharmaceutically acceptable carrier or and adjuvant, thus Bredt does not anticipate Applicant's claimed invention.

Furthermore, Bredt does not anticipate the subject matter of claim 1 or any claim dependent upon claim 1. In particular, the composition of claim 1 comprises an amount of a zwitterionic detergent that is less than the amount required to solubilize the hydrophobic protein at issue. The above passage of Bredt makes clear that the composition obtained in the first step of the method described therein contained CHAPS (i.e., a zwitterionic detergent) in an amount high enough that at least a small amount of the 168 kD protein was dissolved. Thus, the composition of the first step described in Bredt does not meet the above requirement of claim 1 and furthermore does not contain the nonionic detergent that is additionally required by claim 1.

Additionally, neither claim 1 nor claim 35 is anticipated by the octylglycoside containing composition obtained in the second step of the method described in Bredt. Claim 1 requires the presence of certain amounts of a zwitterionic detergent. The octylglycoside containing composition would not contain any residual zwitterionic detergent from the first step. Applicant wishes to point out that Bredt teaches to wash the pellet obtained from centrifugation of the composition of the first step before redissolving it in the octylglycoside containing buffer II; please see column 4, lines 11-12 of Bredt.

Applicant believes that Bredt does not anticipate claims 1-13 or claim 35 of Applicant's claimed invention under 35 USC §102(b) and respectfully requests withdrawal of the rejection.

Rejections under 35 U.S.C §112

Claims 14-16 stand rejected under 35 USC §112, Second Paragraph as allegedly being indefinite for failing to point out and distinctly claiming the subject matter of the invention since claims 14-16 are dependent upon rejected claims.

Applicant's arguments regarding the patentability of claims 1-13 render this rejection moot and respectfully request withdrawal.

Conclusion

In conclusion, this reply is believed to be a full response to the outstanding Office Action. Should any issues remain outstanding or if there are any questions concerning this paper, or the application in general, the Examiner is invited to telephone the undersigned representative at the Examiner's earliest convenience.

Respectfully submitted,

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